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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,291	03/12/2004	Zoltan G. Toth	14669.0064USU1	8286

7590 07/16/2009

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
07/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/800,291	TOTH ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *14,27,60,62,64 and 65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15-26,28-59,61 and 63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/5/09 and 7/6/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-65 are pending, but claims 14, 27, 60, 62, 64 and 65 have been withdrawn as being drawn to non-elected subject matter. As a result, Claims 1-13, 15-26, 28-59, 61 and 63 are examined herein on the merits for patentability. No claim is allowed at this time.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 05 June 2009 and 06 July 2009 are being considered by the examiner.

Declaration under 37 C.F.R. §1.132

The declaration under 37 CFR 1.132 filed 06 July 2009 is sufficient to overcome the rejection of claims 2, 3, 15-26, 29, 30 and 49-59 based upon Villani et al. (US 4,659,716). The declaration is discussed herein below with regards to claims 1, 4-13, 28, 31-48, 61 and 63.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or

newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-13, 15-26, 28-59, 61 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 28 and 37 state, "a weight to weight ratio of about 25% to about 75% of either form to the other". However, it is unclear what is meant by this recitation. It's not clear if Applicants intend form 1 to be present at 20% and form 2 to be present at 80% (and vice versa) relative to the weight of the total mixture (i.e., form 1 is 25% of form 2); or if Applicants intended form 1 to be present at 25% and form 2 to be present at 75% (and vice versa) relative to the weight of the total mixture (i.e., a weight to weight ratio of 25:75). A weight to weight ratio should not be in terms of percentages. The amount of form 1 and form 2 relative to the weight of the mixture can be expressed as percentages, but a weight to weight ratio should not have any units (i.e., weight to weight ratio of 1:3 of form 1 to form 2 indicates 1 unit of form 1 and 3 units of form 2, or 25% form 1 and 75% form 2 relative to the total weight of the mixture). Claims 2, 3, 15, 16, 29, 30 and 49 also recite weight to weight ratios in the form of percentages.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 4-13, 28, 31-48, 61 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Villani et al. (US 4,659,716), as evidenced by Schumacher et al. (US 6,506,767) and the Declaration filed 06 July 2009.

Villani et al. disclose a method for preparing 8-Chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine (desloratadine or descarboxyloratine) as the acetic acid salt (Example III) as well as recrystallization of the free base from hexane (Examples V and VI).

Villani et al. do not disclose that the preparation of desloratadine produces a mixture of polymorph forms I and II. However, Schumacher '767 disclose that the preparation as described by Villani et al. results in a mixture of polymorphs. Therefore, Villani et al. inherently prepared a composition comprising a mixture of polymorphs forms I and II. Also, with regard to the physicochemical properties of the instantly claimed composition, these are inherent properties of a composition that would necessarily be present in the compositions of Villani et al. because the compositions of Villani et al. are within the scope of the compositions of the instant claims.

The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a

scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Also, regarding the claimed ratio of about 25 to about 75% of either form to the other, the Declaration filed 06 July 2009 discloses an example wherein desloratadine acetate in H_2O and K_2CO_3 was stirred at room temperature, extracted with chloroform, washed with H_2O and concentrated to a minimal volume. The material was then precipitated with n-hexane followed by filtering and drying, wherein the obtained desloratadine presented as a mixture of form 1 (25%) and form 2 (75%). This example follows the same procedure as Example V of Villani et al. Therefore, Example V of Villani et al. inherently results in a mixture of form 1 (25%) to form 2 (75%) of desloratadine.

With regard to the compositions prepared in instant claims 37-48, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is

the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, Villani et al. anticipate the product as instantly claimed.

Response to Arguments

Applicant's arguments filed 06 July 2009 have been fully considered but they are not persuasive. Applicant's Declaration presents examples wherein desloratadine was extracted in chloroform, dried or concentrated, and recrystallized or triturated with n-hexane (paras. 11-14 and 16). Two of the examples resulted in form 2 (paras. 12 and 16); one example resulted in a 25:75 ratio of form 1 to form 2 (para. 14); and two examples do not disclose the ratio of forms 1 to 2 (paras. 11 and 13). The Declaration also presents examples wherein desloratadine is suspended in n-hexane at elevated temperature followed by cooling to get solid material (paras. 17-21). Four of the examples resulted in form 1 (paras. 18-21); but one example resulted in a mixture of form 1 to 2 without the ratio being disclosed (para. 17).

The examiner respectfully argues that para. 14 of the Declaration confirms that crystallization of desloratadine by dissolving in chloroform, concentrating to minimal volume, and precipitating with n-hexane results in a 25:75 ratio of form 1 to form 2. Also, para. 17 shows that suspension of desloratadine in n-hexane at reflux followed by cooling to room temperature results in a mixture of forms 1 and 2. The declaration does not disclose the ratios of form 1 and 2 in paras. 11, 13 and 17.

2. Claims 1, 4-13, 28, 31-48, 61 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Schumacher '855 (EP 0 208 855), as evidenced by Schumacher '767 (US 6,506,767) and the Declaration filed 06 July 2009.

Schumacher '855 disclose a method for preparing 8-Chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine (desloratadine or descarboxyloratine) as the acetic acid salt (pg. 26, Example III) as well as recrystallization of the free base from hexane (pg. 29-30, Examples V and VI).

Schumacher '855 do not disclose that the preparation of desloratadine produces a mixture of polymorph forms I and II. However, Schumacher '767 disclose that the preparation as described by Villani et al., which is the same as that disclosed by Schumacher '855, results in a mixture of polymorphs. Therefore, Schumacher '855 inherently prepared a composition comprising a mixture of polymorphs forms I and II. Also, with regard to the physicochemical properties of the instantly claimed composition, these are inherent properties of a composition that would necessarily be present in the compositions of Schumacher '855 because the compositions of Schumacher '855 are within the scope of the compositions of the instant claims.

The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily

make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Also, regarding the claimed ratio of about 25 to about 75% of either form to the other, the Declaration filed 06 July 2009 discloses an example wherein desloratadine acetate in H_2O and K_2CO_3 was stirred at room temperature, extracted with chloroform, washed with H_2O and concentrated to a minimal volume. The material was then precipitated with n-hexane followed by filtering and drying, wherein the obtained desloratadine presented as a mixture of form 1 (25%) and form 2 (75%). This example follows the same procedure as Example V of Villani et al. Therefore, Example V of Villani et al. inherently results in a mixture of form 1 (25%) to form 2 (75%) of desloratadine.

With regard to the compositions prepared in instant claims 37-59, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, Schumacher '855 anticipate the product as instantly claimed.

Response to Arguments

Applicants note that the rejection based on Schumacher '855 is redundant because its disclosure is substantially the same as Villani et al. Applicants note that Schumacher '855 claims priority to 06/838,974 from which Villani et al. issued. Therefore, the examiners response above is incorporated herein by reference.

3. Claims 1, 4-13, 15-26, 28-59 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Piwinski et al. (WO 92/00293) as evidenced by the arguments filed by Quimica Sintetica, S.A. in the Notice of Opposition to European Patent 1 507 531, and further evidenced by the Excerpt from the Opposition proceedings concerning EP 0 993 455 (all documents submitted in the IDS filed 01 October 2008).

Piwinski et al. disclose the preparation of desloratadine from loratadine by treating loratadine with KOH in an ethanol/water mixture at reflux temperature; wherein the desloratadine is extracted with ethyl acetate and dried to give a solid product, and the recovered solid is recrystallized from toluene (pg. 78, Example 1G).

Piwinski et al. do not disclose that the preparation of desloratadine produces a mixture of polymorph forms I and II. However, the Quimica Sintetica state that the preparation as described by Piwinski et al. in Example 1G inherently results in a mixture of polymorph forms I and II (pg. 13, ln. 1-5 and the Table). Also, the Excerpt from the Opposition proceedings concerning EP 0 993 455 provides experimental data showing that recrystallization of desloratadine from toluene results in a mixture of form I to form II of about 20:80, regardless of the starting materials ratio (pg. 7, last two paragraphs). Therefore, in the absence of evidence to the contrary, Piwinski et al. inherently prepared

a composition comprising a mixture of polymorphs forms I and II. Also, with regard to the physicochemical properties of the instantly claimed composition, these are inherent properties of a composition that would necessarily be present in the compositions of Piwinski et al. because the compositions of Piwinski et al. are within the scope of the compositions of the instant claims.

The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

With regard to the compositions prepared in instant claims 37-59, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

though the prior product was made by a different process. See MPEP 2113. Therefore, Piwinski et al. anticipate the product as instantly claimed.

Response to Arguments

Applicants argue on page 12 that Piwinski et al. do not disclose the exact procedure whereby desloratadine is recrystallized. The Declaration shows three possible recrystallization processes wherein either only form 2 was obtained or a mixture of 9:91 forms 1 to 2 was obtained (paras. 8-10). Therefore, Applicants argue that Piwinski et al. fails to necessarily provide a mixture of form 1 to form 2 at about 25% to about 75% of either form to the other, about 20-40% form 2, or about 24-38% form 2, as instantly claimed.

However, the examiner respectfully argues that the most common technique, and one of the simplest, is simple evaporation of the solvent from the solution until the compound is crystallized. Other well-known methods include vapor diffusion, liquid diffusion and sublimation. It is unclear why Applicants chose the cooling technique wherein the compound is dissolved in hot solvent and then allowed to cool at a slow rate to form crystals, which is more complicated than simple evaporation. It is clear from the Excerpt from the Opposition proceedings concerning EP 0 993 455 that recrystallization of desloratadine consistently resulted in an approximately 80:20 ratio of form 1 to form 2. Therefore, Applicants have not clearly shown that the recrystallization according to Piwinski et al. does not result in an approximately 80:20 mixture of form 1 to form 2 desloratadine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-13, 15-26, 28-59, 61 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schumacher et al. (US 6,506,767) in view of Ray et al. (US 6,962,924) and Kou (US 6,100,274).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Schumacher et al. teach the preparation of both polymorph forms 1 and 2 of desloratadine (Examples 1-5). Schumacher et al. further teach that the polymorph form 1 and form 2 desloratadine possess antihistaminic properties (col. 9, ln. 56-61). Schumacher et al. also teach preparation of pharmaceutical formulations comprising said desloratadine (col. 8, ln. 50 through col. 9, ln. 55).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Schumacher et al. do not teach compositions comprising a mixture of polymorph forms 1 and 2 desloratadine in a ratio of 25:75 of either form to the other, 50:50 form 1 to form 2, 55:45 to 65:35 form 1 to form 2, 80:20 to 60:40 form 1 to form 2, or 76:24 to 62:38 form 1 to form 2, as instantly claimed. However, Ray et al. teach that it has been discovered that specific solvent and experimental conditions which consistently produce two distinctly different crystalline polymorphs of desloratadine hemifumarate thereby allowing commercial production of a stochiometrically consistent pharmaceutical product having constant physical properties (col. 2, ln. 9-14). Also, Kou teaches that either form 1 or form 2 desloratadine can be used and both have antihistaminic properties (col. 5, ln. 1-10 and 55-60).

It is noted that Schumacher et al. teach that desloratadine exists as a mixture of polymorphs, and such a mixture could lead to production of a desloratadine product which would exist as a variable mixture of variable composition (i.e., variable percent amounts of polymorphs) having variable physical properties, a situation unacceptable in view of stringent GMP requirements. Therefore, Schumacher et al. teach that the production of a variable mixture of variable composition having variable physical properties is unacceptable. Thus, the production of a mixture of polymorphs would need to produce a consistent mixture with consistent physical properties. Ray et al. teach the production of a mixture of polymorphs forms 1 and 2 desloratadine that results

in consistent physical properties. Therefore, a mixture is acceptable so long as the mixture is consistent with consistent properties.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to prepare a pharmaceutical composition comprising a consistent mixture of polymorphs forms 1 and 2 desloratadine.

Such would have been obvious in the absence of evidence to the contrary because it is generally prima facie obvious to use in combination two or more ingredients that have previously been used separately for the same purpose to form a third composition useful for that same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. *In re Kerkhoven* 626 F.2d 646, 850, 205 USPQ 1069, 1072 (CCPA 1980).

One of ordinary skill in the art would have been able to determine with routine experimentation the preferred ratio of polymorphs form 1 and form 2 desloratadine. The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406

F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on page 13 that Schumacher et al. instructs the public that it is undesirable to use desloratadine polymorphic mixtures in pharmaceutical compositions. However, as discussed above, the examiner respectfully argues that Schumacher et al. reasonably teaches one of ordinary skill in the art that a variable mixture with variable physical properties is unacceptable. Schumacher et al. teach that a form having constant physical properties is desired. Thus, a consistent mixture with constant physical properties is acceptable. Ray et al. teach that a mixture of polymorphs of desloratadine is acceptable with a stochiometrically consistent pharmaceutical product having constant physical properties.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-13, 15-26, 28-59, 61 and 63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 21-24 of copending Application No. 11/283,276 (Toth '276).

More specifically, claims 1-13, 15-26, 28-59, 61 and 63 of the instant application are directed to a stable mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said stable mixture and a pharmaceutically acceptable excipient, wherein said stable mixture comprises: from about 20 wt.% to about 80 wt.% desloratadine Form I; from about 80 wt.% to about 20 wt.% desloratadine Form II; and said stable mixture is made by a process involving one or more organic solvents selected from the group consisting of: n-heptane; toluene;

isopropanol; and mixtures thereof. Claims 14, 27 and 60 of the instant application are directed to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal.

Claims 21-24 of Toth '276 are directed to a mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said mixture, wherein said mixture comprises: from about 35 wt.% to about 82 wt.% desloratadine Form I; from about 65 wt.% to about 18 wt.% desloratadine Form II; and from about 50 ppm to about 4000 ppm of one or more organic solvents selected from the group consisting of: n-hexane; n-heptane; toluene; ethyl acetate; isobutyl acetate; butanol; isobutanol; chloroform; and mixtures thereof. Claim 25 of Toth '276 is directed to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal.

However, while Toth '276 does not claim the physicochemical properties (i.e., melting temperature, stability, flowability, solubility, dissolution rate, and bioavailability) of said stable mixture, as claimed in claims 4-13, 17-26, 31-36, 40-47, 50-59 and 61 of the instant application, it is well within the purview of the skilled artesian to measure the physicochemical properties of said stable mixture by measuring, for example, the melting temperature and resistance to polymorphic transformation, chemical degradation and decomposition that said stable mixture possesses. One of ordinary skill in the art at the time the instant application was filed would have been motivated to conduct routine experimentation in order to determine whether the physicochemical properties (i.e., melting temperature, stability, flowability, solubility, dissolution rate, and

bioavailability) of said stable mixture, to be incorporated into a pharmaceutical formulation, are constant and thus exhibit batch-to-batch consistency and uniformity from a drug manufacturing and quality assurance perspective.

As a result, although claims 1-13, 15-26, 28-59, 61 and 63 of the instant application are not identical to claims 21-24 of Toth '276, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope, with respect to said organic solvents and said weight percent ranges and ratios of crystalline polymorph Form I and Form II of desloratadine, as discussed hereinabove.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It should be mentioned however that while claims 14, 27, 60, 62, 64 and 65 of the instant application are currently withdrawn from further consideration as being directed to a non-elected invention. In the event that the elected product claims are found allowable, the requirement for restriction between the elected product claims and the non-elected method of using claims will be withdrawn, and the rejoined method of using claims will be fully examined for patentability in accordance with 37 CFR 1.104 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 fled. Cir. 1995). In the event of rejoinder, Applicants are advised that claims 14, 27, 60, 62, 64 and 65 of the instant application would be provisionally rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over conflicting claim 25 of Toth '276. This would be a provisional non-statutory double patenting rejection since

conflicting claim 25 of Toth '276 have not yet in fact been patented and are substantially overlapping in scope (i.e., drawn to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal) to claims 14, 27 and 60 of the instant application.

Response to Arguments

Applicant's arguments filed 06 July 2009 have been fully considered. Applicants request that the provisional ODP rejection be held in abeyance until there is an indication of allowable subject matter in the present application. Therefore, the rejection is maintained as discussed above.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/John Pak/
Primary Examiner, Art Unit 1616